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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,035	12/11/2000	Jas C. Lang	22727/04078	9153
7590 08/24/2005			EXAMINER	
Pamela A Docherty Calfee Halter & Griswold 1400 McDonald Investment Center 800 Superior Avenue Cleveland, OH 44114			AEDER, SEAN E	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 08/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/674,035

Applicant(s)

LANG, JAS C.

Examiner

Sean E. Aeder, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 01 April 1905.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,23-25,27 and 28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 23-25, 27, and 28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

***Request for Continued Examination***

The request filed on 06-21-05 for a Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/6874,035 is acceptable and a RCE has been established. An action on the RCE follows.

Claims 2-22 and 26 have been cancelled.

Claim 1 has been amended.

Claims 1, 23-25, 27, and 28 are under examination.

The text of those sections of Title U.S.C. code not included in this Office Action can be found in a prior Office Action.

**Rejections Withdrawn**

The rejection of claims 1, 23-25, 27, and 28 under U.S.C. 112, second paragraph, as being indefinite for reciting "wherein reduced DESC1 expression," alleging it is not clear what the reduction is compared to, is withdrawn in view of the amended claims.

**Rejections Maintained: Response to Arguments**

Claims 1, 23-25, 27, and 28 remain rejected under U.S.C. 112, first paragraph, as failing to comply with the written description requirement. This is a written description rejection.

Claims 1, 23-25, 27, and 28 also remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of detecting the presence of squamous cell carcinoma and prostate cancer in a subject comprising providing a tissue sample suspected of having cancer from the subject of head, neck, or prostate and assaying for the presence of SEQ ID NO:1 or 3 using a sequence of 626-1321 of SEQ ID NO:1 or 3 or SEQ ID NO:5, 6, 7, 8, 9, and 10, wherein the reduced expression of SEQ ID NO:1 or 3 in the sample is compared to a normal match sample is indicative of said cancer, does not reasonably provide enablement for a method of detecting just any DESC1 mRNA by using any nucleic acid that hybridizes with DESC1 mRNA under conditions about 5-20 degrees Celsius below the  $T_m$  of said nucleic acid for the reasons of record and for the reasons set forth below.

In the response filed 4-19-05, Applicants argue that an amendment to claim 1 reciting "... assaying for presence of DESC1 mRNA in the sample, using at least one nucleic acid that hybridizes with the DESC1 mRNA under conditions about 5 to about 20 Celsius below the  $T_m$  of said nucleic acid...", along with numerous working examples, would provide a sufficient written description and enablement of the invention. This argument has been carefully considered but is not found persuasive. The claims remain inclusive of detecting the expression of DESC1 mRNA using any and all nucleic acid sequences and wherein reduced expression, as compared to normal tissue, is indicative of cancer. While applicant has a written description of SEQ ID NO:1 and SEQ ID NO:3 and provides examples of sequences that could hybridize to DESC1

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mRNA, Applicant does not have a written description of, and does not provide enablement for, all variants of DESC1 mRNA or for all nucleic acids that could hybridize to DESC1 mRNA (see pages 4-5 of Action mailed 6/30/04). These rejections could be obviated by limiting the claims to a defined sequence, for which Applicant has a written description, which can specifically hybridize to a SEQ ID NO corresponding to DESC1 mRNA under the conditions recited in claim 1. Thus, applicant's arguments have not been found persuasive and the rejections are maintained.

**The following are NEW GROUNDS of rejection**

Claims 1, 23-25, 27, and 28 are rejected under U.S.C. 112, second paragraph, as being vague and indefinite for reciting the term DESC1 as the sole means of identifying the claimed polypeptide. The use of laboratory designations only to identify a particular molecule renders the claims indefinite because different laboratories may use the same laboratory designations to define completely distinct molecules. Amending the claims to specifically and uniquely identify DESC1 by SEQ ID No can obviate the rejection.

***Conclusion***

No claim is allowed.

**Summary**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Aeder, Ph.D. whose telephone number is 571-272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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**GARY B. NICKOL, PH.D.  
PRIMARY EXAMINER**